

Remarks/Arguments

By virtue of this paper, claims 1, 18, 21, 24, 27, and 28 are sought to be amended, claims 2-17, 19, 20, 22, 23, 25, 26, 29 and 30 are sought to be canceled, claims 31-32 are withdrawn where claim 31 is sought to be withdrawn but currently amended and Claims 33-39 are added New. The amendments are believed not to introduce new matter, and their entry is respectfully requested. The cancellations and amendments are made without prejudice or disclaimer. Claims 1, 18, 21, 24, 27, 28, 31, 32 and 33-39 are respectfully presented for consideration further in view of the below remarks.

Elections/ Restriction

Claim of Group II 31, 32 are withdrawn and presently amended to further clarify applicant's invention and to include all the limitations of generic claim 1 to allow rejoinder of these claims. Amendments are fully supported by specification and figures as originally filed. No new matter is believed or intended to be introduced by these amendments. As claims of Group II, 31, 32 are withdrawn and presently amended (See MPEP 714, permitting amendments to withdrawn claims) to include all the limitations of elected generic claim 1, applicant respectfully respect withdrawal of Election/ Restriction requirements and rejoin the claims of Group II 31 and 32.

Claim Objections

The examiner is thanked for continuing examination, and thereby furthering prosecution. Appropriate corrections are done to overcome objections.

Claim Rejections - 35 U.S.C. § 112

On page 3 of Final Office Action mailed on Feb, 17, 2010, the Examiner rejected Claims **2-3, 7-8, 14-15, 18, 21, 24, 27** under 35 U.S.C. § 112, second paragraph. The Examiner is thanked for continuing examination, and thereby furthering prosecution. Applicant has cancelled claims **2, 3, 7, 8, 14, 15** and amended claims **18, 21, 24, 27** so that there is proper antecedent basis and to further define Applicant's invention. No new matter has been introduced in amended claims. Amendments are believed to overcome the rejection under 35 U.S.C. § 112, second paragraph.

Claim Rejections - 35 U.S.C. § 102

Claim 1 is rejected under **35 U.S.C. 102(b)** as being anticipated by Marino (US 4,733,654.) .Applicant respectfully requests entry of amended independent Claim 1. Claim 1 has been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification at, e.g. paragraphs **[[0002], [0005], [0016], [00028], [00040], [00086], [00087], [00096], Figs.9, 28 and 31.** Applicant submits that "Marino" (US 4,733,654) does not suggest or teach or disclose each and every feature or element of amended claim 1.

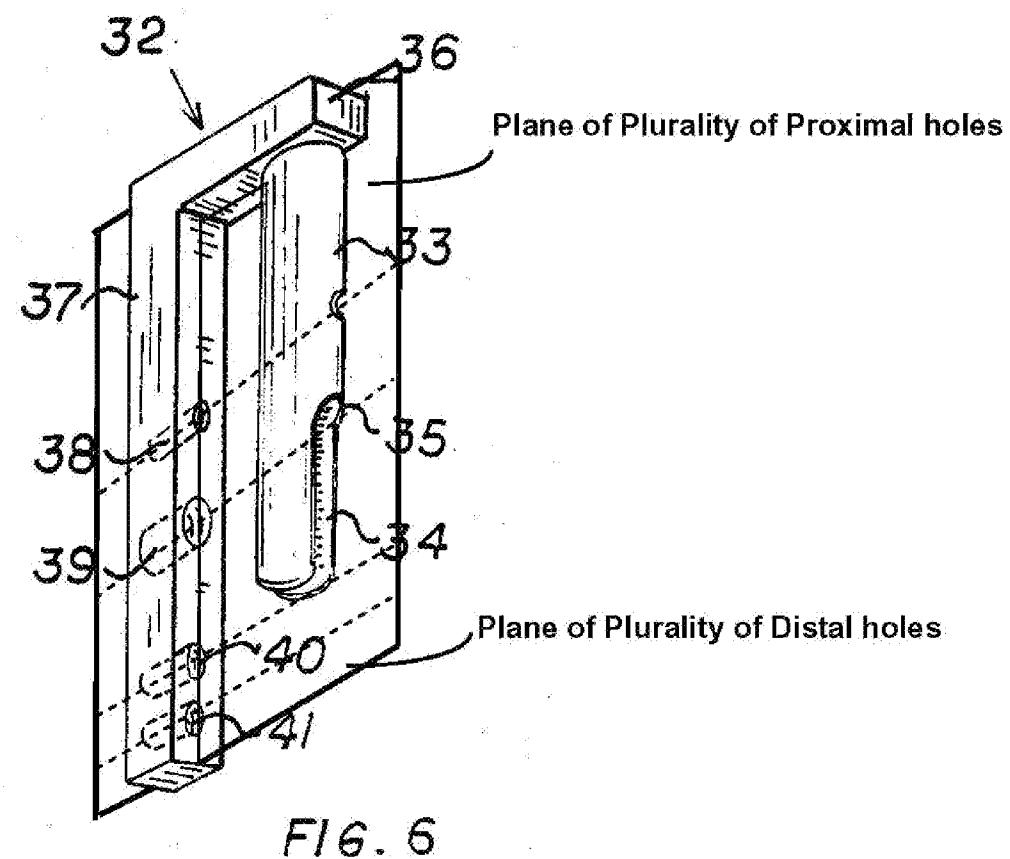
1. Kit of combinations disclosed by Marino comprises a standard routine intramedullary nail 1 like Kuntscher couples with extension 2 where extension 2, also illustrated in FIG. 2, has a distal tip 3 with conical threads 4 dimensioned to match the female thread 5 in the proximal head 6 of the nail 1 (Col. 2 ll 30-50, Figs 1, 2). Thus intramedullary nail disclosed by Marino is two piece nail with joint with thread attachment. This threaded joint weakens the assembly by creating stress riser at junction and there are all chances of opening up of joint during rotation. Marino further discloses "The distal tip 3 of the extension 2 is also drilled orthogonally to form two additional 'bores 22, 23 which are in line with symmetrical bores 24 and 25 in the proximal end of the nail 1. Threaded pins 26 and 27 engage said bores in order to stabilize the proximal end of the nail 1. For further stability the side plate 19 is captured at its lower end 5 through bores 31 by pins 26 and 27 (Marino Col 2 line 67 – Col 3 line 6). Marino further discloses and recommends to install a grommet 28 into lined up bores 23 and 25 as well as bores 22 and 24 to immobilize extension member 20 within the nail member 1 in order to prevent rotation in between nail 1 and extension member 2 (Marino Col 3 line 43-45), so it seems that Marino nail assembly has too many joints and that makes the assembly weaker and joining these elements will certainly hamper accuracy and precision while targeting with the help of drill guide. Applicant **claims** structurally a one piece intramedullary nail to avoid these drawbacks. Thus intramedullary nail disclosed by Marino is structurally two piece nail with joint and require additional enhancements (Marino Col 2 line 67 – Col 3 line 6, Marino Col 3 line 43-45) to add stability , while intramedullary nail claimed

by applicant is structurally one piece nail without any joint

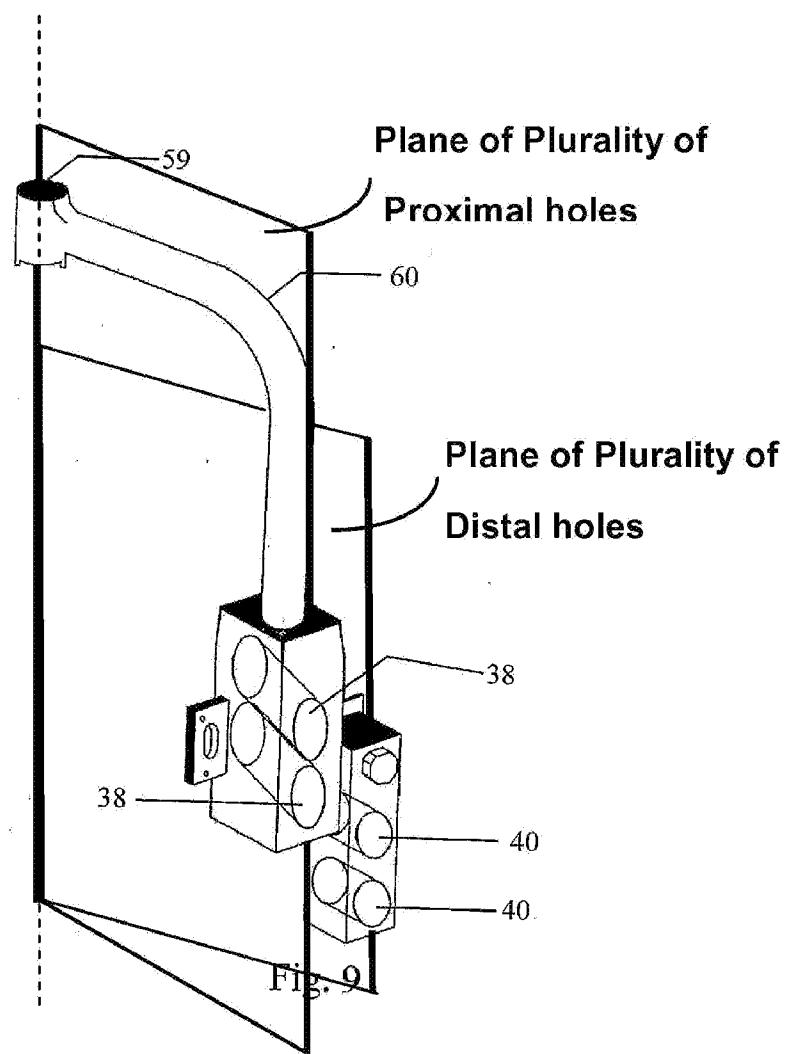
2. Applicant further traverses the Examiner's characterizations of Marino and each of the rejections. Examiner characterize Marino's reference in Final action Paper Page 4-6 (Fig.1 and Col3 lines 15-60) and on page 5 and other Figure on page 6 and 15 and response to argument page 18 .Examiner here points out that Marino does teaches and discloses that the plane of centre of first plurality proximal holes in Nail intersects with plane of center of first plurality of distal holes in nail as explained by Examiner in Fig on page 6 and 15 labeling and showing planes intersecting with each other. Applicant respectfully traverses this observation and argument of examiner pointing out that proximal centerline (not plane of center of first plurality of proximal holes) and distal centerline (not plane of center of first plurality of proximal holes) does intersect with each other as shown in Fig in Final office action on Page 6 and Page 15, but they intersect on same plane and plane of centre of proximal holes and plane of center of distal holes do not intersect and they are placed in one single plane only. Applicant respectfully submits detailed arguments for such traversal as below. As disclosed by Marino (Col 2 line 35-65, Col 3 line 1-60) and Fig 1, 2, 3,4, 5 and 6 :

- a) Drilling guide 32 having guide member 37 extending distally and parallel to nail member 1 and extension member 2. Marino further discloses guide member 37 has block of proximal holes having bores 38 and 39 where bore 38 is to be aligned with hollow barrel member 14 of side plate 19 and proximal sleeved hole 9 of extension member 2 , bore 39 to be aligned with proximal unsleeved small bore 20 of extension member 2 and small bore in positioning leg 33 . Marino further discloses block of distal holes having bores 40 and 41, where bore 40 is to be aligned with holes 31 of side plate 19, distal bores 22, 23 of extension member 2 and bores 24, 25 of proximal end of nail 1. Block of proximal holes and block of distal holes in Drilling guide member 37 are not offset with each other vertically or horizontally and they are lying in one plane only.

Applicant respectfully requests examiner to see Fig 6 of Marino showing Drilling guide 32 - perspective side view with planes of first plurality of proximal holes and plane of first plurality of distal holes - both are same planes, plurality of proximal holes 38, 39 and plurality of distal holes 40 and 41 are in one line and plane and not offset with each other horizontally or vertically. (See Fig.6 Below of Marino - Emphasis added).



Applicant respectfully points out that structure of implant assembly as disclosed and claimed by applicant comprises "a block of a second plurality of proximal holes and a block of a second plurality of distal holes having their placement offset vertically and horizontally on targeting device in different intersecting planes". (See Fig.9 Below of Applicant's present application - Emphasis added)



b) Extension Member 2 having proximal holes – sleeved large bore 9 to receive barrel member 14 of side plate 19 with composite pin 11 and unsleeved small bore 20 for smaller pin 21, distal bores 22 and 23 to be aligned with bores 24 and 25 of proximal end of nail 1 with the help of grommet 28. Proximal Bore 9 to be further aligned with bore 39 of drill guide arm 37, proximal bore 20 to be aligned with bore 38 of drill guide arm 37 and small hole in positioning leg 33, distal bore 22 to be aligned with bore 40 of drill guide arm 37, distal bore 23 to be aligned with bore 41 of drill guide arm 37. Applicant points out that placement of proximal holes 9 and 20 on nail extension member 2 to be aligned respectively with barrel 14 and proximal holes 39 and 38 of drill guide arm 37 ; and placement of distal holes 22 and 23 on extension member 2 to be aligned with distal holes 31 of side plate 19, distal bores 40 and 41 of guide arm 37 are in same plane . (See Fig.2 and 3 Below of Marino - Emphasis added).

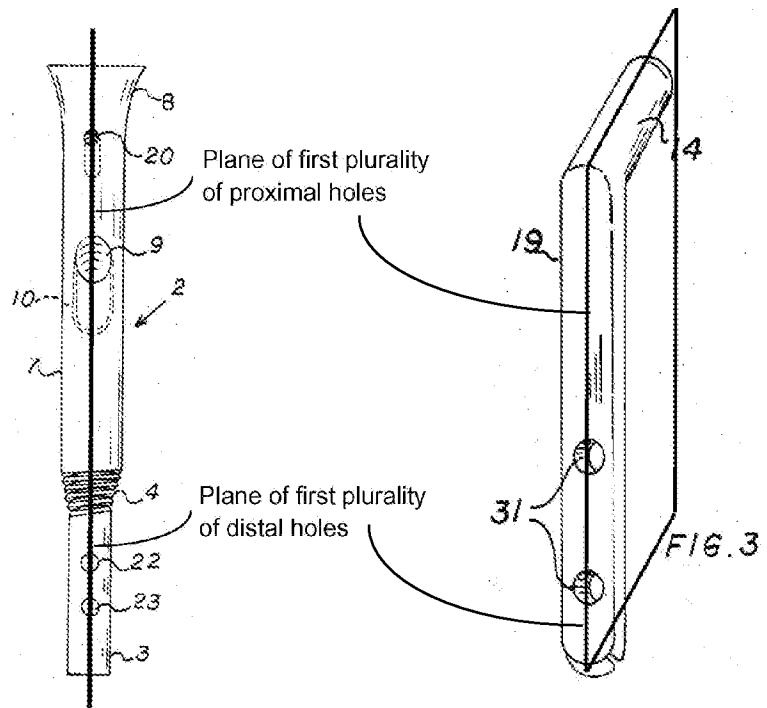


FIG. 2

Applicant respectfully points out that structure of implant assembly as disclosed and claimed by applicant comprises "a first plurality of proximal holes and a first plurality of distal holes having their placement on intramedullary nail in different planes and these planes intersects". (See Fig.28 Below of Applicant's present application - Emphasis added)

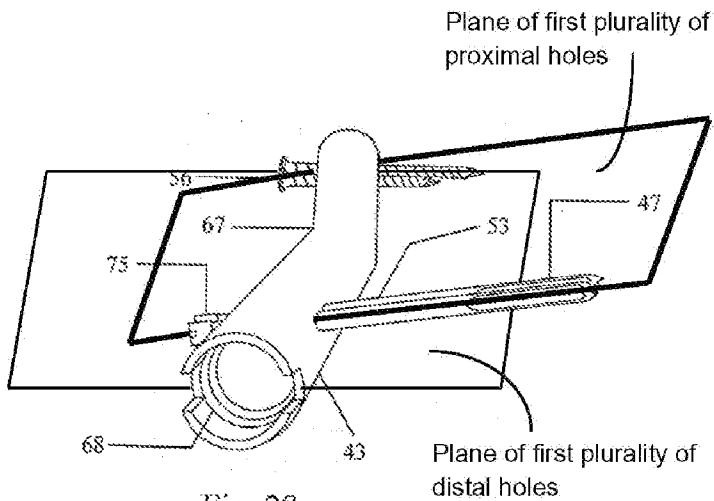


Fig. 28

According to teaching and disclosure of Marino for making assembly, first piece extension member 2 (having proximal bores 9 and 20, distal bores 22 and 23 aligned in one line) to be joined by male -female threads with second piece Nail member 1 where bores 22, 23 of extension member aligned with bores 24 and 25 of nail member 1 and this joint is enhanced by grommet 28 through bores 22-24 and bores 23-25, further bores 22-24 and bores 23-25 to be aligned with bores 31 in side plate 19 and bores 40, 41 of guide member 37, and further proximal bore 9 to be aligned with bore 39 of targeting arm 37 and center of barrel member 14 of side plate, proximal bore 20 of extension member 2 to be aligned with bore 38 in targeting guide arm 37 and small hole in positioning leg 33 (Where proximal bores 39, 38 and distal bores 40, 41 of targeting guide member 37 are in one line and not placed offset vertically or horizontally). Proximal bores 39, 38 and distal bores 40, 41 of targeting guide member placed in one plane and they are aligned with proximal bores 9 and 20 of extension member, center of barrel member 14 of side plate 19, distal bores 22,23,24,25 of extension member 2 and Nail 1 and distal holes 31 of side plate 19 – all are in one plane only. So applicant respectfully submit that Marino does not teach expressly or inherently to have a first plane of center of first plurality of proximal holes and a second plane of center of first plurality of distal holes intersecting with a first plane. (See Fig 2, 3, 6 of Marino (emphasis added), Col 2

line 35-65, Col 3 line 1-60 and Fig 9, 28 (emphasis added) and 31 of Applicant's Application).

3. Marino discloses a first bore 9 surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11 with its engagement with barrel of side plate 19 (Marino Col 2 line 47-50). This type of arrangement as taught by Marino where barrel 14 placed through bore 9 with sleeve 10 in extension member 2 requires large opening-bore in extension member 2 leading to further weakening of nail walls and to accommodate larger diameter hole – diameter of extension member 2 has to be substantially large which will require more reaming of bone tissue and loss of bone near fracture area, hampering healing of fracture (Emphasis added), which is contrary to Applicant's disclosure where applicant discloses and claims structure of proximal holes of intramedullary nail allowing substantially small diameter of nail which will require minimal reaming of medullary canal and preserve more bone tissue.
4. Marino describes structure of a first bore 9 (Proximal holes) surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11 with its engagement with barrel of side plate 19, where barrel 14 angularly joined with side plate 19. Applicant discloses structure of proximal holes in Intramedullary Nail without any tubular sleeve surrounding within the hole and barrel member is not joined with buttress plate and barrel is not placed through proximal holes of nail
5. Marino further discloses drilling guide 32 comprises a tubular positioning leg 33 shaped and dimensioned to engage into the proximal end 8 of the extension 2. It should be noted that the positioning leg 33 is not threaded but fits snugly into the extension 2.(Marino Col 3 . line 15-22) Applicant discloses structure of connecting end of targeting device and connecting end of intramedullary nail coupled or mounted by threaded connecting bolt for better fitting for accuracy of targeting jig.
6. Applicant points out that as disclosed by Marino (Fig. 1,5 and 6) positioning leg 33 is also drilled with bore 38 corresponding to the position of bore 20 in the extension and the second pin 21, looking to Fig 2, 5 and 6 after targeting bore 20 in extension member 2 through bore 38 in positioning leg 33 and fixing it with suitable anchor or screw , bifurcate arms of positioning leg 33 will be firmly fixed with extension member 2 and will not allow disengagement of targeting guide arm from extension member after surgery is complete. Applicant discloses and claims structure of intramedullary nail connectable to targeting device which allows disengagement of targeting device from intramedullary nail after surgery is complete.

Accordingly, Marino does not teach or describe, expressly or inherently, each and every element as set forth in amended claim 1 nor does Marino have elements arranged as required by this amended claim 1. As such, Marino does not anticipate or render obvious independent claim 1 as a whole. Applicant respectfully requests entry and allowance of Claim 1.

Claim Rejections under 35 U.S.C. § 103

Claim 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marino US 4,733,654 in view of Judet et al US 5,591,168 and Engelhardt et al US 4,805,607.

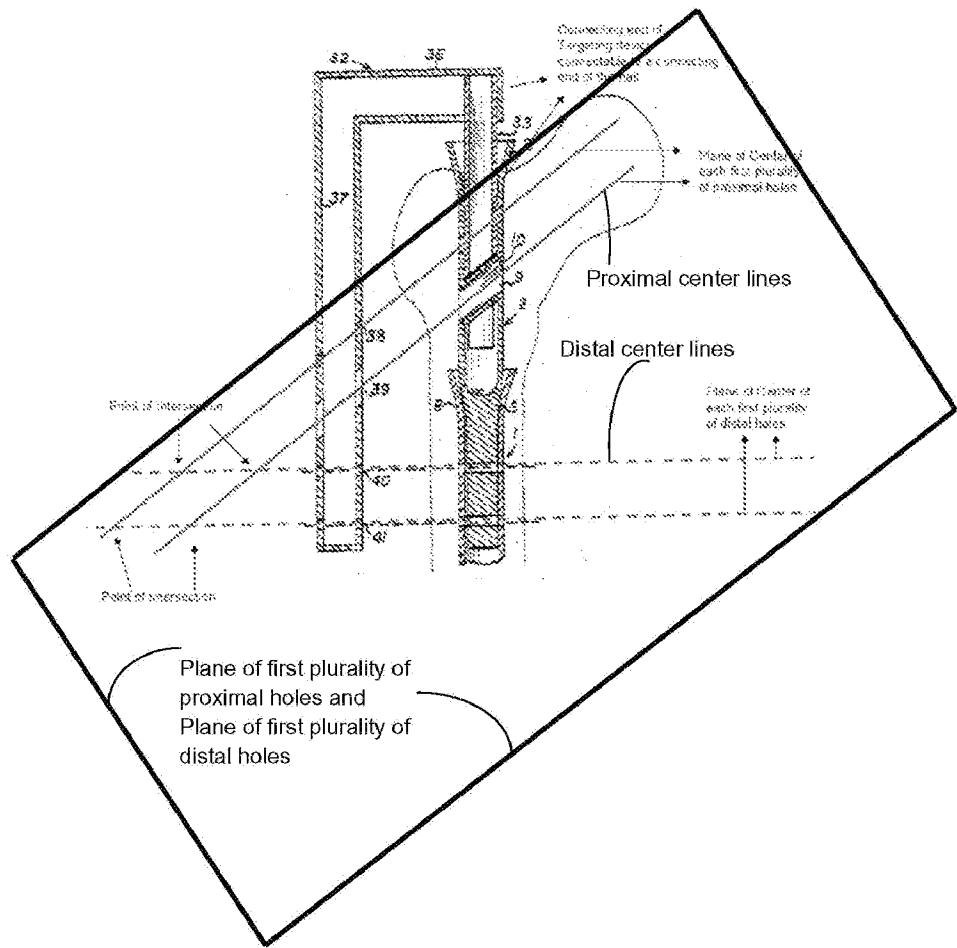
Applicant respectfully requests entry of amended dependent Claim 27 and Independent claim 28. Independent Claim 1, dependent Claim 27 and Independent claim 28 have been amended to further describe Applicant's invention. Support for such amendments may be found throughout the specification, at, e.g. paragraphs **[0002], [0005], [0016], [[0024][00028], [00036][00040], [00048][00086], [00087], [00089], [00092], [00093][00096], Figs. 3, 9, 15, 21, 24, 25, 28, 30 and 31.** Without acquiescing to any of the contentions in the Outstanding Office Action, it is respectfully asserted that the according to amended claim 1, 27, 28 and other claims, present invention is constructed structurally different from device of Marino, device of Judet or Engelhardt and it is used in an entirely different manner, thereby overcoming drawbacks in the Kit and method of Marino, device of Judet and Engelhardt et al either singly or in combination with Marino, as well as many similar devices known in the prior art of record.

1. Kit of combinations disclosed by Marino comprises a standard routine intramedullary nail 1 like Kuntscher couples with extension 2 where extension 2, also illustrated in FIG. 2, has a distal tip 3 with conical threads 4 dimensioned to match the female thread 5 in the proximal head 6 of the nail 1 (Col. 2 ll 30-50, Figs 1, 2). Thus intramedullary nail disclosed by Marino is two piece nail with joint with thread attachment. This threaded joint weakens the assembly by creating stress riser at junction and there are all chances of opening up of joint during rotation. Marino further discloses "The distal tip 3 of the extension 2 is also drilled orthogonally to form two additional 'bores 22, 23 which are in line with symmetrical bores 24 and 25 in the proximal end of the nail 1. Threaded pins 26 and 27 engage said bores in order to stabilize the proximal end of the nail 1. For further stability the side plate 19 is captured at

its lower end 5 through bores 31 by pins 26 and 27 (Marino Col 2 line 67 – Col 3 line 6). Marino further discloses and recommends to install a grommet 28 into lined up bores 23 and 25 as well as bores 22 and 24 to immobilize extension member 20 within the nail member 1 in order to prevent rotation in between nail 1 and extension member 2 (Marino Col 3 line 43-45), so it seems that Marino nail assembly has too many joints and that makes the assembly weaker and joining these elements will certainly hamper accuracy and precision while targeting with the help of drill guide. Applicants **claims** structurally one piece intramedullary nail to avoid these drawbacks. Thus intramedullary nail disclosed by Marino is structurally two piece nail with joint and additional enhancements while intramedullary nail claimed by applicant is structurally one piece nail without any joint overcoming drawbacks of structure of Intramedullary nail of Marino as mentioned earlier in above paragraph.. Marino's two piece nail with too many joints does not satisfy structural limitation of Applicant's one piece nail structure capable to impart rotational stability and accuracy and precision of surgery.

2. Applicant further traverses the Examiner's characterizations of Marino and each of the rejections. Examiner characterize Marino's reference in Final action Paper Page 7-17 (Fig.1 and Col3 lines 15-60) and Figure on 15 and response to arguments page 18 .Examiner here points out that Marino discloses and does teach that the plane of centre of first plurality proximal holes in Nail intersects with plane of center of plurality of first plurality of distal holes in nail as explained in Fig. labeling and showing planes intersecting with each other. Applicant respectfully traverses this observation and argument of examiner pointing out that proximal centerline (not plane of center of first plurality of proximal holes) and distal centerline (not plane of center of first plurality of proximal holes) does intersect with each other as shown in Fig in Final office action on Page 6 and Page 15, but they intersect on same plane and plane of centre of proximal holes and plane of center of distal holes do not intersect and they are placed in one single plane only. (See Fig below

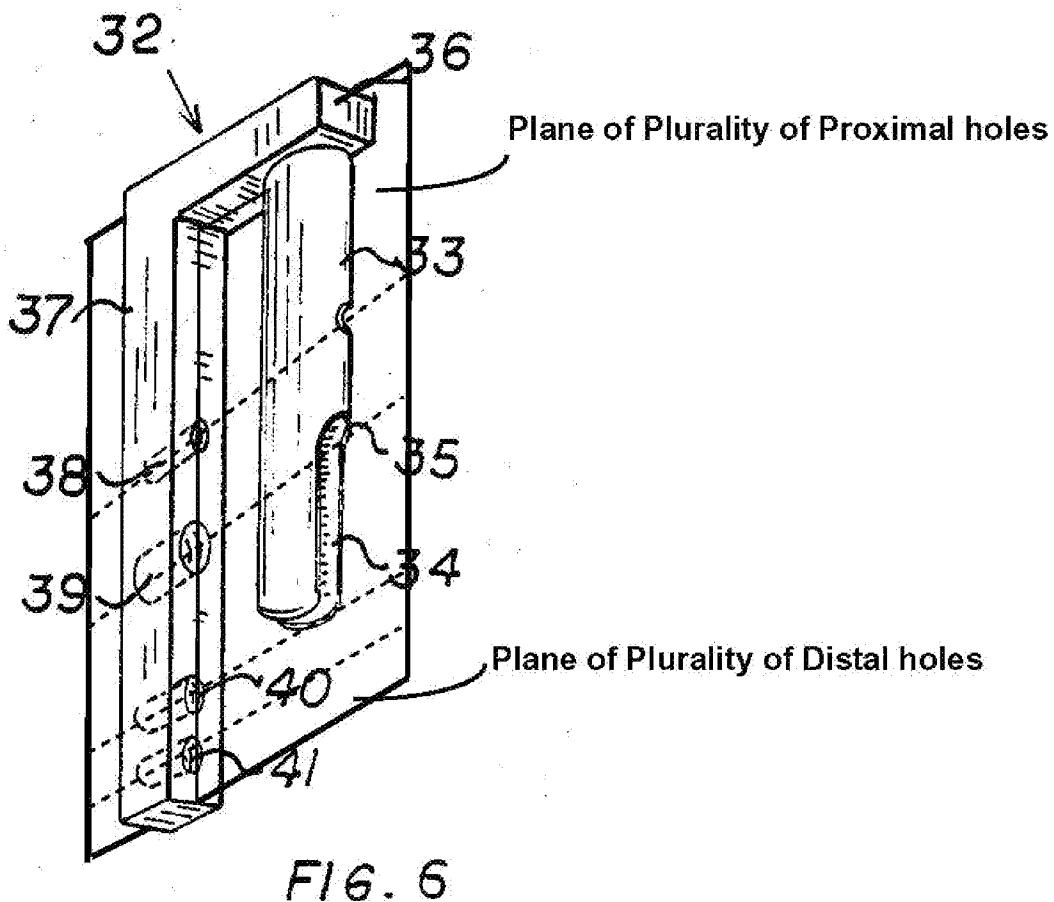
presented by examiner labeled as planes of first plurality of proximal holes and planes of first plurality of distal holes, plane shown by applicant – emphasis added)



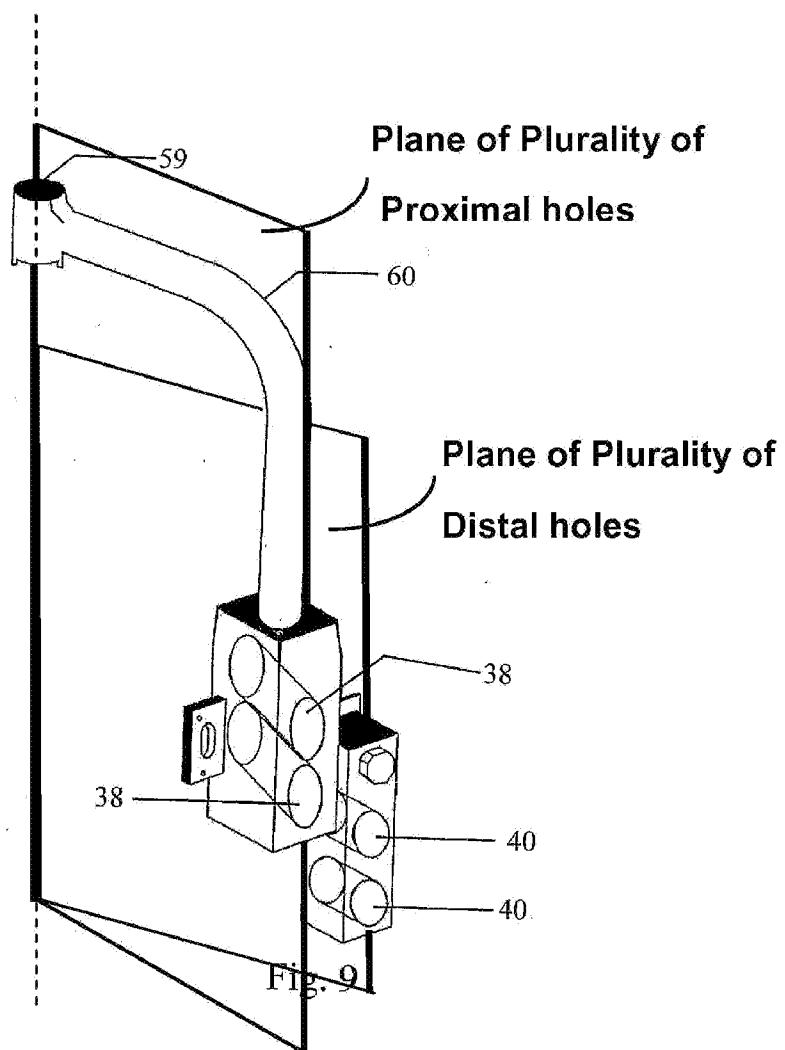
Applicant respectfully submits detailed arguments for such traversal as below. As disclosed by Marino (Col 2 line 35-65, Col 3 line 1-60) and Fig 1, 2, 3,4, 5 and 6 :

- Drilling guide 32 having guide member 37 extending distally and parallel to nail member 1 and extension member 2. Marino further discloses guide member 37 has block of proximal holes having bores 38 and 39 where bore 38 is to be aligned with hollow barrel member 14 of side plate 19 and proximal sleeved hole 9 of extension member 2 , bore 39 to be aligned with proximal unsleeved small bore 20 of extension member 2 and small bore in positioning leg 33 . Marino further discloses block of distal holes having bores 40 and 41, where bore 40 is to be aligned with holes 31 of side plate 19, distal bores 22, 23 of extension member 2 and bores 24, 25 of proximal end of nail

1. Block of proximal holes and block of distal holes in Drilling guide member 37 are not offset with each other vertically or horizontally and they are lying in one plane only. Applicant respectfully requests examiner to see Fig 6 of Marino showing Drilling guide 32 - perspective side view with planes of first plurality of proximal holes and plane of first plurality of distal holes - both are same planes, plurality of proximal holes 38, 39 and plurality of distal holes 40 and 41 are in one line and plane and not offset with each other horizontally or vertically. (See Fig.6 Below of Marino - Emphasis added)



Applicant respectfully points out that structure of implant assembly as disclosed and claimed by applicant comprises "a block of a second plurality of proximal holes and "a block of a second plurality of distal holes having their placement offset vertically and horizontally on targeting device in different intersecting planes". (See Fig.9 Below of Applicant's present application - Emphasis added)



b) Extension Member 2 having proximal holes – sleeved large bore 9 to receive barrel member 14 of side plate 19 with composite pin 11 and unsleeved small bore 20 for smaller pin 21, distal bores 22 and 23 to be aligned with bores 24 and 25 of proximal end of nail 1 with the help of grommet 28. Proximal Bore 9 to be further aligned with bore 39 of drill guide arm 37, proximal bore 20 to be aligned with bore 38 of drill guide arm 37 and small hole in positioning leg 33, distal bore 22 to be aligned with bore 40 of drill guide arm 37, distal bore 23 to be aligned with bore 41 of drill guide arm 37. Applicant points out that placement of proximal holes 9 and 20 on nail extension member 2 to be aligned respectively with barrel 14 and proximal holes 39 and 38 of drill guide arm 37 ; and placement of distal holes 22 and 23 on extension member 2 to be aligned with distal holes 31 of side plate 19, distal bores 40 and 41 of guide arm 37 are in same plane . (See Fig.2 and 3 Below of Marino - Emphasis added).

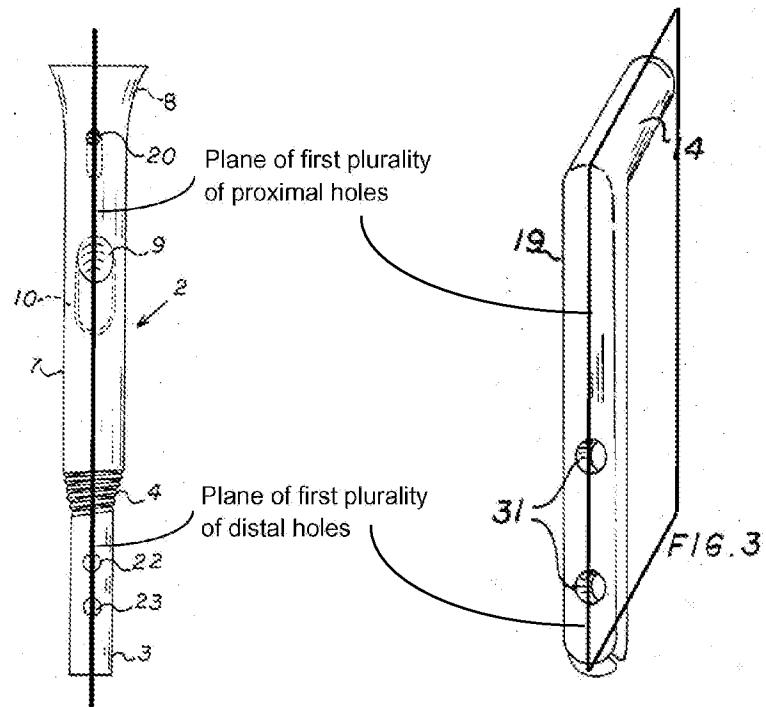


FIG. 2

Applicant respectfully points out that structure of implant assembly as disclosed and claimed by applicant comprises "a first plurality of proximal holes and a first plurality of distal holes having their placement on intramedullary nail in different planes and these planes intersects". (See Fig.28 Below of Applicant's present application - Emphasis added)

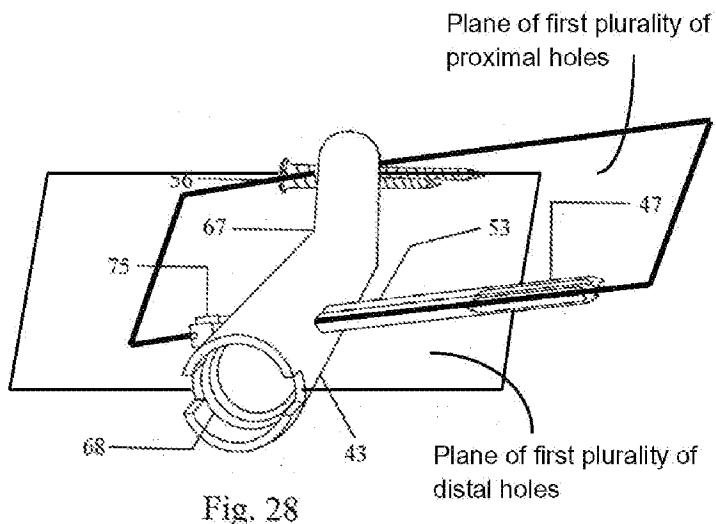


Fig. 28

3. Marino discloses a first bore 9 surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11 with its engagement with barrel of side plate 19 (Marino Col 2 line 47-50). This type of arrangement as taught by Marino where barrel 14 placed through bore 9 with sleeve 10 in extension member 2 requires large opening-bore in extension member 2 leading to further weakening of nail walls and to accommodate larger diameter hole – diameter of extension member 2 has to be substantially large which will require more reaming of bone tissue and loss of bone near fracture area, hampering healing of fracture (Emphasis added), which is contrary to Applicant's disclosure where applicant discloses and claims structure of proximal holes of intramedullary nail allowing substantially small diameter of nail which will require minimal reaming of medullary canal and preserve more bone tissue.
4. Marino describes structure of a first bore 9 (Proximal holes) surrounded by tubular sleeve 10 is placed transversely and obliquely in body 7 of extension member 2 to receive composite fixation pin 11 with its engagement with barrel of side plate 19, where barrel 14 angularly joined with side plate 19.

Applicant discloses structure of proximal holes in Intramedullary Nail without any tubular sleeve surrounding within the hole and barrel member is not joined with buttress plate and barrel is not placed through proximal holes of nail

5. Marino further discloses drilling guide 32 comprises a tubular positioning leg 33 shaped and dimensioned to engage into the proximal end 8 of the extension 2. It should be noted that the positioning leg 33 is not threaded but fits snugly into the extension 2. (Marino Col 3 . line 15-22) Applicant discloses structure of connecting end of targeting device and connecting end of intramedullary nail coupled or mounted by threaded connecting bolt for better fitting for accuracy of targeting jig.
6. Applicant points out that as disclosed by Marino (Fig. 1,5 and 6) positioning leg 33 is also drilled with bore 38 corresponding to the position of bore 20 in the extension and the second pin 21, looking to Fig 2, 5 and 6 after targeting bore 20 in extension member 2 through bore 38 in positioning leg 33 and fixing it with suitable anchor or screw , bifurcate arms of positioning leg 33 will be firmly fixed with extension member and will not allow disengagement of targeting jig from extension member after surgery is complete. Applicant discloses and claims structure of intramedullary nail connectable to targeting device which allows disengagement of targeting device from intramedullary nail after surgery is complete.

Present invention overcomes the above mentioned drawbacks found in the Marino or other like apparatus common in prior art by providing structure and construction and placement of a first plurality of proximal holes and first plurality of distal holes in intramedullary nail along with corresponding second plurality of proximal holes and second plurality of distal holes in targeting device such that plane of center of a first plurality of proximal holes in intramedullary nail is extending to midsection of head and neck portion of femur bone and is intersecting with plane of center of first plurality of distal holes of intramedullary nail . (Present application Para ([0005], [0016], [00028], [00040], [00086], [00087], [00096], **Figs.9, 28 and 31**).

The structural combination of elements set forth in the amended claim1, **27 and 28**, as well as the manner, in which that structural combination of elements is used, is distinctly different from that disclosed in Marino and subject matter of claim 1, 27 and 28 of present invention is neither anticipated nor rendered obvious by the reference.

For claim 27 and Claim 28 replacing Judet's side plate with shouldered plurality of barrels in place of Marino's side plate does not provide solutions to deficiency of Kit of Marino. For example for inserting a plurality of angled barrel member with side plate as disclosed by Marino and Judet requires large incision by open method and

tissue dissection of lateral cortex which is already broken very badly having less blood supply from soft tissue and will require large diameter drilling for plurality of angled barrel member 18 which will lead to further weakening of lateral cortex of femur bone which is already broken very badly and further hampering platform for controlled collapse of fracture gap, which teaches away from applicant's disclosure of minimal invasiveness. Applicant points out that with applicant's invention, buttress plate 50 having narrow obtuse end 84 is滑动 on surface of greater trochanter 3 and lateral cortex 22 of femur from first small incision at tip of greater trochanter 3 and structure of slit 86 in plurality of large holes helps in positioning of buttress plate on guide pins at second small incision at lateral cortex 22 without much soft tissue dissection (Present application Para [00093], [00096], Figs 24, 25). . Applicant respectfully argues that side plate 19 provided by Judet does not have structure of slit in proximal barrels, so one has to make large incision and much of soft tissue dissection to place side plate 19 on lateral cortex of femur bone . Applicant respectfully argues that Kit provided by Marino has composite fixation pin 11 to engage head and neck of femur through angled barrel member 18 of plate 19 across through bore 9 in extension member 1 and now according to combination of Judet with Marino one more barrel member is accommodated across through bore 20 of extension member of Marino requiring to enlarge that small hole 20 in extension member leading to further weakening of nail wall of extension member and creating stress riser and in turn one has to increase diameter of extension member 2 to overcome weakness of wall of extension member 2 leading to either difficult and forceful insertion of large diameter nail in medullary canal or to have option of enlarging the medullary canal by more reaming and invasion to bony tissue which is already deficient in old age patients having generally fracture in this area of junction of head-neck and shaft of femur. Applicant discloses contrarily to that barrel members 51 not across through (Present Application Fig. 21 and 30) the proximal holes 37 of intramedullary nail 42 to keep diameter of head part 43 intramedullary nail 42 smaller to avoid more reaming of bony tissue and to avoid much force for insertion leading to minimal invasion to patient . Present invention disclosed and claimed by applicant provides even distribution of forces due to structure and construction of planes of proximal holes and distal holes intersecting with each other, capable of fixation of fractures in two different intersecting planes,

providing dynamic mechanical fixation with one piece unitary nail having strength with precision and minimal invasion to patient. Marino does not suggest, teach or give any motivation to a person of ordinary skill in art to arrive at independent claim 1 or 27 or 28 of present invention. So applicant respectfully argues that applicant's claims 1,27 and 28 are as a whole structurally and functionally different from disclosed Marino's kit and even on application of teachings of Judet side plate on Marino's kit does not yield predictable and improved results leading to improved resultant assembly and also modification of Marino's kit in view of side plate of Judet or combining teachings of references does not suggest, teach or give any motivation to a person of ordinary skill in art to arrive at independent claim 28 or dependent claim 27 of present invention.

Applicant respectfully further argues that Engelhardt et al US 4,805,607 discloses a modular two piece intramedullary nail 20 comprised of two major components , namely an elongated base nail 22(Col.3 II 50 – Col. 4 II 1-35, Figs. 2-3) and an extension member 24 intended for elective attachment to one end of base nail by a complex joint. The modular intramedullary nail 20 comprising base member is intended for the repair of long bone fractures, most notably femur and tibia and further described that, the base nail 22 is intended for placement in medullary canal of long bone like femur and preferably curved to a radius of approximately 60 to 80 inches. Engelhardt et al further teaches that mid region of base nail 22 has very deeply fluted or tri-flanged cross section shape and an extreme tip 28 of base nail at its leading end is moderately blunt, displaying a radius , for example , of approximately 0.125 inches, at trailing end of base nail 22 , the flanges 26 are faired into cylindrical bearing region 32 and a pair of generally parallel , spaced apart, engagement tongs 34 extending away from bearing region 32 and are resilient in directions toward and away from each other for locking with extension member. Applicant respectfully argue that the structure of nail having base member 22 here is intended to be placed into hollow medullary cavity as opposite to applicant's intention to use such hip pin in cancellous dense packed bone of head and neck of femur bone which is *not modular* or has *no curvature* and it has sliding surface and fixed slidably through the a first plurality of holes of intramedullary nail, a plurality of barrels and central large holes of buttress plate and it has at its trailing end no element of structure for locking with any extension member and at leading end it has

triflanged surface and not at mid region.

Examiner argues on Page 17 of final office action "It would have also been obvious to one having ordinary skill in the art to modify the combination of Marino and Judet to include a tri-flanged tip in view of Engelhardt because it allows bone contact along three very thin flanges of metal....." Applicant in response further argues that combining reference of Engelhardt for triflanged part does not yield same predictable results as with claimed structural limitation of a triflanged part having *mores taper* in plurality of Proximal Hip Pins as claimed by applicant . Applicant claims triflanged part having *mores taper as a structural limitation* for better fixation due to structure *having mores taper* and *Engelhardt's triflanged tip is not having structure of mores taper* at leading end. So even after modifying combination of Marino and Judet to include triflanged tip in view to Engelhardt, modification of combination does not arrive at claimed proximal hip pin of Applicant having *structural limitation of mores taper.*

Intramedullary nail disclosed by Engelhard et al have same disadvantages as Marino's Kit. Modification of Marino's kit in view of Intramedullary Nail of Engelhard et al or combining teachings of references does not suggest, teach or give any motivation to a person of ordinary skill in art to arrive at Independent claim 28 or dependent claim 27 of present invention.

Applicant further argues that Middleton claims a *in situ formed anchor* where it is *essential to form a pilot hole in the bone having first diameter and forming a cavity in bone* connected with pilot hole and distal to pilot hole having second diameter *which is substantially larger than first diameter* and also requires to have performed implant element having holes as interlocking elements wherein there is *substantial space between interlocking elements and boundary of said cavity*, injecting a hardenable material into cavity to make insitu formed anchor to hold bone. Applicant points out that in situ anchor provided by Middleton is not the same as fixation assembly as described and claimed by applicant in present claim 24. For example, with Applicant's claimed invention, proximal hip pin comprising triflanged part with multiple holes is *specifically in direct contact with cancellous bone* and not within any bone cavity that means there is *no any substantial space* between the triflanged part with multiple holes and bony tissue of head and neck of femur. This is not taught by

Middleton. Middleton does teach to form a cavity surgically with the help of cavitations devices before placing anchoring implant in bone and teaches to have substantial space between placed implant and boundary of cavity where placed anchoring implant is not in direct contact with bony tissue, which is contrarily to Applicant's teaching. Making a cavitations in bone having substantially large diameter than the shaft or body of screw and filling this large cavity with cement or any harden able material has drawbacks of further weakening the bone and necrosis due to exothermic reaction to large amounts of such artificial material and it does not allow to have more than one anchors in head and neck of femur which is many a times essential to have for rotational stability and better fixation in osteoporotic bone in elderly , Applicant further points out that having substantially large cavity and having space between performed element and cavity boundary , in cases where cavity is filled only partially there will be no full bondage between performed anchoring element and bone leading to loss of fixation and there will not be any second chance to improve the fixation. Together with arguments and the reasons set forth above, Applicant herewith has shown that Middleton does not make obvious applicants invention. Applicant respectfully requests rejection of claim under USC 103 (a) be removed. Applicant respectfully requests rejection of dependent claims 18, 21, 24, 27, under USC 103 (a) to be removed. In reference to above remarks and arguments.

Conclusion

Consideration for and allowance of the pending claims in this Application, as provided in the Listing of Claims beginning on page two of this paper are respectfully requested for the reasons set forth herein. In light of amendments, remarks and arguments presented with this paper, Applicant respectfully submit that the pending and amended claims are in condition for allowance. No new matter has been introduced with this Amendment. This amendment is timely filed under CFR 1.116. No additional fees are believed due with this response.

Any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the cited references show or teach, even if not expressly discussed herein. Although changes to the claims have been made, no acquiescence or estoppels is or should be implied thereby; such amendments are made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. If the undersigned pro se inventor has overlooked a relevant teaching in any of the references, the Examiner is requested to point out specifically where such teaching may be found.

If the Examiner has any question or comments or if further clarification is required and if it is believed that an interview might be useful, Applicant respectfully requests examiner to contact the undersigned pro se inventor at the telephone number: +91 9825387016 or indicate such questions or clarifications or requirement to contact. Applicant thanks examiner for suggestion of securing services of patent attorney, but applicant is unable to do so due to very high cost involved. Applicant thanks examiner for allowing prosecution by pro se inventor and guiding the inventor.

Respectfully submitted,

Date: April 3, 2010

/Navin N Thakkar/

39/B, Hindu colony,

Signature

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